UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,947	10/16/2003	Dongmei Xu	79601	4552

21559 7590 10/30/2006

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
ZHENG, LI	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/686,947	XU, DONGMEI	
	Examiner	Art Unit	
	Li Zheng	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *2-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ~~1062005~~. 1/6/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-2, and SEQ ID NO: 181 in the reply filed on 8/31/2006 is acknowledged. Claim 2 does not read on elected SEQ ID NO: 181. Therefore it is considered as non-elected subject matter and withdrawn from consideration. The non-elected subject matter must be removed from claims.

The requirement is deemed proper and is therefore made FINAL.

Priority

2. Support for the elected sequence of SEQ ID NO: 181 can be found in U.S. Provisional Application No. 60/503,989 filed on 3/12/2002 (SEQ ID NO: 33), and 60/485,368 filed on 7/8/2003 (SEQ ID NO: 35).

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The hyperlinks shown on Specification page 26, lines 5 and page 65, line 17 need to be disabled.

4. The disclosure is objected to because of the following informalities:

The recitations, "southern blotting/hybridization", in specification needs to be changed to --Southern blotting/hybridization--. For example, the recitation is found on page 47, line 17 and page 49, line 24.

Appropriate correction is required.

Claim Objections

5. Claim 1 is objected to because it contains non-elected sequences.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well-established utility.

The claimed nucleotide sequence comprising SEQ ID NO: 181 are not supported by a specific and/or substantial asserted utility because the disclosed use of SEQ ID NO:181 is not specific and is generally applicable to any P450 gene. The specification states that "the reduction or elimination or over-expression of P450 enzymes in Nicotiana plants may be accomplished using RNA viral systems" (page 6, lines 17-20) and that "resulting transformed or infected plants are assessed for phenotypic changes including, but not limited to, analysis of endogenous p450 RNA transcripts, P450 expressed peptides, and concentrations of plant metabolites using techniques commonly available to one having ordinary skill in the art" (page 7 lines 22-27). However, cytochrome P450 enzymes are involved in a wide variety of diverse biochemical pathway in plants. The specification states that "cytochrome p450s, also known as p450 heme-thiolate proteins, usually act as terminal oxidases in multi-component electron transfer chains, called p450-containing monooxygenase systems. Specific reactions catalyzed include demethylation, hydroxylation, epoxidation, N-oxidation, sulfooxidation, N-, S- and O- dealkylations, desulfation, and deamination reactions as well as reactions involving the reduction of azo, nitro, and N-oxide group" (pages 1, lines 19-26). The specification admits that the diverse role of tobacco P450 enzymes has been implicated in affecting a variety of plant metabolites such as phenylpropanoids, alkaloids, terpenoids, lipids, cyanogenic glycosides, glucosinolates and a host of other chemical entities (the paragraph bridging pages 1-2) and the P450 enzyme and their broadening roles in plant constituents is still being discovered (page

2, lines 14-16). The specification does not teach which of these roles SEQ ID NO:181 is involved in.

Applicants present an approach to clone full length cDNA of P450 genes or fragments thereof. There are 33 groups of p450 genes identified and differential expression pattern for some of the P450 genes were confirmed (pages 50-53). However, this fails to provide a specific and substantial utility for the claims. First, the differential expression data for SEQ ID NO:181 is not presented in the specification. Second, differential expression itself does not constitute a specific utility, since there are 33 groups of P450 genes identified by Applicants using this method, for example, SEQ ID NO: 149-297 (pages 66-67, table III). Therefore, it is concluded that all of the aforementioned are non-specific uses that are applicable to any P450 gene fragment in general and not particular or specific to the nucleotide sequence of SEQ ID NO:181 being claimed.

A nucleotide sequence may be utilized to silence a gene or overexpress a gene. However, the need for such research clearly indicates that the protein and /or its function is not disclosed as to a currently available or substantial utility. In this case, the transgenic plants, if any, that are to be produced as final products resulting from processes involving SEQ ID NO:181 do not have any asserted or identified specific and substantial utilities. The research contemplated by applicants to lower or eliminate the expression of the P450 gene, or to overexpress the gene (page 71, lines 13-19) does not constitute a specific and substantial utility. In addition, identifying and studying the properties of a protein itself or the mechanisms in which the protein is involved in does

not define a "real world" context or use. Further basic research is required to determine how to use the claimed plants produced by the claimed method. Similarly, the other listed and asserted utilities as summarized above or in the instant specification are neither substantial or specific due to being generic in nature and applicable to a myriad of such compounds. Note, because the claimed invention is not supported by a specific and substantial asserted utility for the reasons set forth above, credibility has not been assessed. Neither the specification as filed nor any art of record discloses or suggests any property or activity for the nucleotide sequence such that another non-asserted utility would be well established for the compounds.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 1 is rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ohshima et al. (1987, FEBS LETTERS 225:243-246).

Ohshima et al. teach PR-1 gene from tobacco (page 245, Fig. 2). An isolated nucleic acid molecule from Nicotiana, wherein said nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO:181 (emphasis added) in claim 1 encompasses any DNA from Nicotiana that has any dinucleotide sequence in SEQ ID NO: 181, and PR-1 gene certainly contains a dinucleotide sequence in SEQ ID NO: 181.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.

1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claim 1 is are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 70 of copending Application No. 11/116,881. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 70 of copending Application No. 11/116,881 is drawn to a expression cassette comprising a nucleotide sequence including the sequence from Figure 100, which represent SEQ ID NO: 190 in copending Application No: 11/116,881, which have 100% identity to SEQ ID NO:181 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No.10/934,944. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of copending Application No.10/934,944 is drawn to an isolated nucleic acid molecule from Nicotiana, wherein the nucleic acid

molecule is SEQ ID NO: 181 of copending Application No.10/934,944, which is 100% identical to SEQ ID NO: 181 of the instant claim.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Claim 1 is rejected.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Zheng whose telephone number is 571-272-8031. The examiner can normally be reached on Monday through Friday 9:00 AM - 6:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER